

FEB 22 2012

**510(K) SUMMARY****Smartheart****510(k) Number K_____**

Applicant's Name: SHL Telemedicine International Ltd.
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Trade Name: Smartheart

Preparation Date November 20, 2011

Classification: **Name:** Telephone electrocardiograph transmitter and receiver
Product Code: DXH
Regulation No: 21 CFR 870.2920
Class: II
Panel: Cardiovascular

Device Description: The *Smartheart* is a personal, hand-held battery powered, 12 lead ECG and rhythm strip device with Bluetooth connection. The *Smartheart* acquires ECG data via attached electrodes. The *Smartheart* transmits the data in real-time to a suitable Bluetooth communication device for forwarding it to a remote location and a certified medical professional capable of interpreting the results.

Intended Use Statement:

The *Smartheart* device is intended to condition an electrocardiographic signal so that it can be transmitted digitally via Bluetooth technology and cell-phone or communication device to a remote location. The *Smartheart* device is designed to be used by a patient to transmit a 12 lead ECG and rhythm strip in real-time to enable review at a physician's office, hospital or other medical receiving center.

**Predicate Devices:**

The *Smartheart* is substantially equivalent to the following predicate device:

Device Name	510k No	Date of Clearance
CardioSen'C™	K080047	Jul 11, 2008

Performance Standards:

The *Smartheart* device has been tested according to various standards and guidance documents, such as IEC 60601-2-51:2005 (Essential performance, of recording and analyzing single channel and multichannel electrocardiographs), IEC 60601-2-25 (1993) +A1:1999 (requirements for the safety of electrocardiographs), etc.

Usability study:

SHL Telemedicine has conducted a usability study designed to test the effectiveness of the *Smartheart* device as a 12 lead ECG transmitter. The results of the study clearly confirmed the efficacy of the *Smartheart* as a 12 lead ECG transmitter.

Conclusions:

The *Smartheart* device has similar intended use and technological concepts as the market-cleared CardioSen'C™. The *Smartheart* is capable of transmitting the electrocardiographic signal digitally so it can be forwarded to a remote location as the market-cleared CardioSen'C™. The results of tests, analyses, and studies performed with the *Smartheart* device clearly demonstrate that the *Smartheart* device is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

FEB 22 2012

SHL Telemedicine International, Ltd.
c/o Mr. Yoram Levy
Qsite
31 Haavoda St.
Binyamina, Israel 30500

Re: K113514
Trade/Device Name: Smartheart
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitters and Receivers
Regulatory Class: Class II (two)
Product Codes: DXH
Dated: November 20, 2011
Received: November 28, 2011

Dear Mr. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K113514

Device Name: Smarteart

Indications for Use: The *Smarteart* device is intended to condition an electrocardiographic signal so that it can be transmitted digitally via Bluetooth technology and cell-phone or communication device to a remote location. The *Smarteart* device is designed to be used by a patient to transmit a 12 lead ECG and rhythm strip in real-time to enable review at a physician's office, hospital or other medical receiving center.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)

Division of Cardiovascular, Respiratory and Neurological Devices

510(k) Number


(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113514